



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kathleen M. Miller et al.
Application No.: 10/789,398
Date Filed: 02/27/2004
Title: Implantable Or Insertable Medical Device Resistant To Microbial Growth And Biofilm Formation
Examiner: Unassigned
Group Art: 3738
Docket: 98-P0151US2

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Missing Parts
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial Number
10/071,840

U.S. Filing Date
02/08/2002

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. The following additional information is provided for the Examiner's consideration:

III. CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

FEES

IV. **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b):** (check one box)

- a. within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
- b. within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
- c. before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
- d. before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

V. **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c):** (check one box)

before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).

- a. No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
- b. See the statement below. No fee is required.

VI. **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):**

on or before payment of the issue fee and is accompanied by the following:

- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
- 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).

VII. **STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)**

The undersigned hereby states that

- a. each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
- b. no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
- c. some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

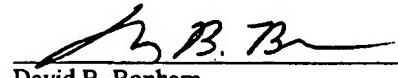
VIII. **PAYMENT OF FEES**

- A check in the amount of _____ is enclosed for the above-identified fee(s).
- Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
- If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
- Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,
Mayer Fortkort & Williams, PC



David B. Bonham
Attorney for Applicant
Reg. No. 34,297
Tel. 703-433-0510

Mayer Fortkort & Williams, PC
Customer Number 27774

Enclosures: PTO/SB/08
 References
 Foreign Search Report
 Other:

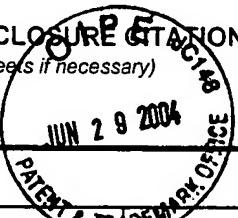
Certificate of Mailing By First Class Mail

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail under 37 CFR 1.8 in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 6/25/03.

Marjorie Scariati
(Printed name of Person Mailing Correspondence)

marjorie scariati
(Signature)

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)



ATTY DOCKET NO.
98-PO151 US2

SERIAL NO.
10/789,398

Kathleen M. Miller et al.

FILING
02/27/04

GROUP
3738

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
1.	4,054,139	10/18/77	Crossley	128	260	
2.	4,240,163	12/23/80	Galin	3	13	
3.	4,472,327	9/18/84	Neefe	264	1.9	
4.	4,603,152	7/29/86	Laurin et al.	604	265	
5.	4,723,950	2/9/88	Lee	604	322	
6.	4,731,080	3/15/88	Galin	623	6	
7.	4,853,978	8/8/89	Stockum	2	167	
8.	4,902,503	2/20/90	Umemura et al.	424	83	
9.	4,923,450	5/8/90	Maeda et al.	604	265	
10.	4,933,178	6/12/90	Capelli	424	78	
11.	4,946,899	8/7/90	Kennedy et al.	525	244	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
1.	WO 97/14447	4/24/97	PCT	A61L 27	00	✓	
2.	WO 99/47595	9/23/99	PCT	CO8K 3	00	✓	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1.	Swartz, R., et al., "Biofilm Formation on Peritoneal Catheters Does Not Require the Presence of Infection," <i>ASAIO Trans.</i> , Vol. 37, no. 4, Oct.-Dec. 1991, pp. 626-634.
2.	Richards, G.K., et al., "Comparative Rates of Antibiotic Action Against <i>Staphylococcus epidermidis</i> Biofilms," <i>ASAIO Trans.</i> , Vol. 37, no. 3, Jul.-Sept. 1991, pp. M160-162.

EXAMINER	DATE CONSIDERED
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
12.	4,978,391	12/18/90	Jones	106	35		
13	5,080,892	1/14/92	Yamamori et al.	424	78.09		
14.	5,091,205	2/25/92	Fan	427	2		
15.	5,091,442	2/25/92	Milner	523	122		
16.	5,098,379	3/24/92	Conway et al.	604	51		
17.	5,102,401	4/7/92	Lambert et al.	604	264		
18.	5,102,402	4/7/92	Dror et al.	604	265		
19.	5,130,159	7/14/92	Shlenker et al.	427	2		
20.	5,135,516	8/4/92	Sahatjian et al.	604	265		
21.	5,137,671	8/11/92	Conway et al.	264	130		

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

3.	Stamm, Walter E., "Catheter-Associated Urinary Tract Infections: Epidemiology, Pathogenesis, and Prevention," <i>American Journal of Medicine</i> , Vol. 91, no. 3B, Sept. 1991, pp. 65S-71S.
4.	Golomb, Gershon, et al., "Prevention of Bacterial Colonization on Polyurethane <i>in vitro</i> by Incorporated Antibacterial Agent," <i>Journal of Biomedical Materials Research</i> , Vol. 25, no. 8, Aug. 1991, pp. 937-952.

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	22	5,165,952	11/24/92	Solomon et al.	427	2	
	23.	5,171,318	12/15/92	Gibson et al.	623	5	
	24.	5,178,870	1/12/93	Schaeken et al.	424	405	
	25.	5,217,493	6/8/93	Raad et al.	623	11	
	26.	5,261,896	11/16/93	Conway et al.	604	265	
	27.	5,272,012	12/21/93	Opolski	428	423.1	
	28.	5,304,121	4/19/94	Sahatjian	604	53	
	29.	5,328,954	7/12/94	Sarangapani	524	589	
	30.	5,344,411	9/6/94	Domb et al.	604	265	
	31.	5,360,415	11/1/94	Yabushita et al.	604	265	
	32.	5,362,754	11/8/94	Raad et al.	514	566	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	5.	Mulhall, Anne, "Biofilms and Urethral Catheter Infections," <i>Nursing Standard</i> , Vol. 5, no. 18, Jan. 23-29, 1991, pp. 26-28.
	6.	Chang, Chung Che, et al., "Effect of <i>Staphylococcus epidermidis</i> on Adherence of <i>Pseudomonas aeruginosa</i> and <i>Proteus mirabilis</i> to Polymethyl Methacrylate (PMMA) and Gentamicin-Containing PMMA," <i>Journal of Orthopaedic Research</i> , Vol. 9, no. 2, Mar. 1991, pp. 284-288.

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
33.	5,366,505	11/22/94	Farber	623	11	
34..	5,370,681	12/6/94	Herweck et al.	623	1	
35.	5,389,314	2/14/95	Wang	264	25	
36.	5,409,012	4/25/95	Sahatjian	128	749	
37.	5,462,644	10/31/95	Woodson	204	131	
38.	5,599,298	2/4/97	Sahatjian	604	49	
39.	5,607,683	3/4/97	Capelli	424	405	
40.	5,611,354	3/18/97	Alleyne	128	846	
41.	5,616,119	4/1/97	Davis	604	19	
42.	5,624,704	4/29/97	Darouiche et al.	427	2.24	
43.	5,643,207	7/1/97	Rise	604	93	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

7.	Liedberg, H., et al., "Pseudomonas aeruginosa: Adherence to and Growth on Different Urinary Catheter Coatings," <i>International Urology and Nephrology</i> , Vol. 22, no. 5, 1990, pp. 487-492.
8.	Anwar, Hosmin, et al., "Testing the Susceptibility of Bacteria in Biofilms to Antibacterial Agents," <i>Antimicrobial Agents and Chemotherapy</i> , Vo. 34, no. 3, 1990, pp. 2043-2046,

EXAMINER	DATE CONSIDERED
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INFORMATION DISCLOSURE CITATION
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FILING
02/27/04

GROUP
3738

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
44.	5,679,399	10/21/97	Shlenker et al.	427	2.3	
45.	5,707,366	1/13/98	Solomon et al.	604	265	
46.	5,716,406	2/10/98	Farber	623	11	
47.	5,741,331	4/21/98	Pinchuk	623	11	
48.	5,772,640	6/30/98	Modak et al.	604	265	
49.	5,853,745	12/29/98	Darouiche	424	423	
50.	5,902,283	5/11/99	Darouiche et al.	604	265	
51.	6,083,208	7/4/2000	Modak et al.	604	265	
52.	6,106,505	8/22/2000	Modak et al.	604	265	
53.	09/734,639		Pinchuk et al.			12/12/00

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

9.	Dunne, W. Michael Jr., "Effects of Subinhibitory Concentrations of Vancomycin or Cefamandole on Biofilm Production by Coagulase-Negative Staphylococci," <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 34, no. 3, Mar. 1990, pp. 390-393.
10.	Doughterty, Steven H., et al., "Endogenous Factors Contributing to Prosthetic Device Infections," <i>Infectious Disease Clinics of North America</i> , Vol. 3, no. 2, June 1989, pp. 199-209.

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INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Docket Number (Optional) 98-PO151 US2	Application Number 10/789,398
Applicant(s) Kathleen M. Miller et al.	
Filing Date 02/27/04	Group Art Unit 3738

*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
11.	Speer, Anthony G., et al., "Biliary Stent Blockage with Bacterial Biofilm," <i>Annals of Internal Medicine</i> , Vol. 108, no. 4, Apr. 1998, pp. 546-553
12.	Liedberg, H., et al., "Silver Coating of Urinary Catheters Prevents Adherence and Growth of <i>Pseudomonas Aeruginosa</i> ," <i>Urological Research</i> , Vol. 17, no. 6, 1989, pp. 357-358.
13.	Ramsay, J.W.A., et al., "Biofilms, Bacteria, and Bladder Catheters: A Clinical Study," <i>British Journal of Urology</i> , Vol. 64, no. 4, Oct. 1989, pp. 395-398.
14.	Farber, Bruce F., et al., "The Use of Nonsteroidal Antiinflammatory Drugs to Prevent Adherence of <i>Staphylococcus epidermidis</i> to Medical Polymers," <i>Journal of Infectious Diseases</i> , Vol. 166, no. 4, Oct., 1992, pp. 861-865.
15.	Farber, Bruce F., et al., " <i>Staphylococcus epidermidis</i> Extracted Slime Inhibits the Antimicrobial Action of Glycopeptide Antibiotics," <i>Journal of Infectious Diseases</i> , Vo., 161, no.1, Jan. 1990, pp. 37-40.
16.	Donnenfeld, E.D., et al., "Biofilm and Bacterial Adherence Inhibition with Sodium Salicylate," <i>Investigative Ophthalmology & Visual Science</i> , Vol. 35, no. 4, 1994, p. 2164.
17.	Farber, B.F., et al., " <i>Staphylococcus aureus</i> Extracted Polysaccharide Interferes with the Antimicrobial Action of Glycopeptide Antibiotics," <i>Clinical Research</i> , Vol. 38, no. 2, 1990, p. 428A.
18.	Farber, B.F., et al., "Extracted <i>S. epidermidis</i> Slime Interferes with the Antimicrobial Action of Glycopeptide Antibiotics," <i>Clinical Research</i> , Vol. 37, no. 2, 1990, p. 428A.
19.	Farber, B.F., et al., "Unique Properties of <i>S. epidermidis</i> Extractable Polysaccharide Slime (SEEP)," <i>Clinical Research</i> , Vol. 36, no. 3, 1988, p. 455A.
20.	Teichberg, Saul, et al., "Salicylic Acid Decreases Extracellular Biofilm Production by <i>Staphylococcus epidermidis</i> : Electron Microscope Analysis," <i>Journal of Infectious Diseases</i> , Vol. 167, no. 6, 1993, pp. 1501-1503.
21.	Farber, Bruce F., et al., "A Novel Antibiofilm Technology for Contact Lens Solutions," <i>Ophthalmology</i> , Vol. 102, no. 5, May 1995, pp. 831-836.

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) 98-PO151 US 2		Application Number 10/789,398		
		Applicant(s) Kathleen M. Miller				
		Filing Date 02/27/04	Group Art Unit 3738			
		*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
22.	Roberts, E.L., et al., "The Role of Sodium Salicylate in the Prevention of the Adherence of Acanthamoeba Castellanii to Unworn Contact Lenses," <i>Investigative Ophthalmology & Visual Science</i> , Vol. 35, no. 4, 1994, p. 2150.					
23.	Donnenfeld, Eric D., et al., "Controlled Evaluation of a Bandage Contact Lens and a Topical Nonsteroidal Antiinflammatory Drug in Treating Traumatic Corneal Abrasions," <i>Ophthalmology</i> , Vol. 102, no. 6, June 1995, pp. 979-984.					
24.	Costerton, J. William, et al., "Bacterial Biofilms in Nature and Disease," <i>Annual Review of Microbiology</i> , Vol. 41, 1987, pp. 435-464.					
25.	Parsons, C. Lowell, et al., "Inhibition of Sodium Urate Crystal Adherence to Bladder Surface by Polysaccharide," <i>Journal of Urology</i> , Vol. 134, no. 3, Sept. 1985, pp. 614-616.					
26.	Kingston, D., et al., "Self-disinfecting Plastics for Intravenous Catheters and Prosthetic Inserts," <i>Journal of Hygiene, Cambridge</i> , Vol. 96, 1986, pp. 185-198.					
27.	Speer, A.G., et al., The Role of Bacterial Biofilm in Clogging of Biliary Stents," Dept. Gastroenterology, Middesex Hospital, London UK, Dept. Biology, University of Calgary, Alberta, Canada.					
28.	Sherman, Stuart, et al., "Stent-induced Pancreatic Ductal and Parenchymal Changes: Correlation of Endoscopic Ultrasound with ERCP," <i>Gastrointestinal Endoscopy</i> , Vol. 44, no. 3, 1996, pp. 276-282.					
EXAMINER			DATE CONSIDERED			

***EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/789,398
				Filing Date	02/27/04
				First Named Inventor	Kathleen M. Miller et al.
				Group Art Unit	3738
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	98-PO151 US2

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English Language Translation is attached.

Sheet 8 OF 9

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				Docket Number (Optional) <u>98-PO151US2</u>		Application Number <u>10/789,398</u>	
				Applicant(s) <u>Kathleen M. Miller et al.</u>			
				Filing Date <u>02/27/04</u>	Group Art Unit <u>3738</u>		
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	56	5,569,463	19-1996	Helmus et al.	424	426	
	57	6,475,434	11-2002	Darouiche	422	28	
	58	4,036,227	07-1997	Zaffaroni et al.	424	428	
	59	5,468,787	11-1995	Braden et al.	523	113	
	60	6,482,830	11-2002	Redkar et al.	514	283	
FOREIGN PATENT DOCUMENTS							
REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	29	Anthony G. Gristina et al., "Bacterial Adherence and the Glycocalyx and Their Role in Musculoskeletal Infection," <i>Orthopedic Clinics of North America</i> , Vol. 15, no. 3, July 1984, pp. 517-535.					
	30	F. Ikeda et al., "Formation of Biofilm by Slime Producing <i>Staphylococcus epidermidis</i> and Bactericidal Activity of Cefazolin," <i>Kansenshogaku Zasshi. Journal of the Japanese Association for Infectious Diseases</i> , Vol. 65, no. 7, July 1991, pp. 875-882.					
EXAMINER				DATE CONSIDERED			
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